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Substitute for form 1449A/PTO

Complete if Known

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Application Number	10/719,734
Filing Date	November 21, 2003
First Named Inventor	Solomon S. Steiner
Group Art Unit	1616
Examiner Name	Alstrum Acevedo, James Henry
Attorney Docket Number	PDT 120/121 DIV CON

Sheet 1 of 14

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		3,906,950		Cocozza	09-23-1975	
		3,921,637		Bennie, et al.	11-25-1975	
		4,153,689		Hirai	05-08-1979	
		4,196,196		Tiholiz	04-01-1980	
		4,211,769		Okada	07-08-1980	
		4,272,398		Jaffe	06-09-1981	
		4,294,829		Suzuki	10-13-1981	
		4,659,696		Hirai	04-21-19	
		4,861,627		Mathiowitz	08-29-1989	
		4,866,051		Hunt	09-1989	
		4,946,828		Markussen	08-07-1990	
		5,006,343		Benson	04-09-1991	
		5,042,975		Chien	08-27-1991	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		EP	0/069/715		Draco AB	01-12-1983		
		EP	0/122/036		Teijin Ltd	10-17-1984		
		EP	0/237/507		Draco AB	09-16-1987		
		EP	0 257 915		Innovata Biomed Ltd.	02-03-1988		
		EP	0/360/340		Akzo	03-28-1990		
		EP	0/364/235		Toyo Jozo Kabushiki	04-18-1990		

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		Group Art Unit	1616		
		Examiner Name	Alstrum Acevedo, James Henry		
Sheet	2	of	14	Attorney Docket Number	PDT 120/121 DIV CON

EP	0606486	Teijin Ltd.	12-23-1993
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U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		5,145,684		Liversidge, et al.	09-08-1992	
		5,188,837		Domb	02-1993	
		5,204,108		Illum	04-20-1993	
		5,260,306		Boardman, et al.	11-09-1993	
		5,354,562		Platz	10-11-1994	
		5,364,838		Rubsamen	11-15-1994	
		5,458,135		Patton, et al.	10-17-1995	
		5,482,927		Maniar	01-09-1996	
		5,484,606		Dhabar, et al.	01-16-1996	
		5,492,112		Mecikalski, et al.	02-20-1996	
		5,514,646		Chance, et al.	05-07-1996	
		5,562,909		Allcock, et al.	10-08-1996	
		5,577,497		Mecikalski, et al.	11-26-1996	

FOREIGN PATENT DOCUMENTS								
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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		EP	0655237		Hoechst AG	03-26-1996		
		EP	0748213		Inhale Therapuetic Sys	12-18-1996		
		EP	1/114/644		Genetech, Inc.	07-11-2001		
		EP	96911738		Nektar Therapeutics	06-16-2004		

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Sheet	3	of	14	Attorney Docket Number	PDT 120/121 DIV CON

	GB	2,240,337		National Research Development Corp.	07-31-1991		
	JP	0149545		Taisho Pharmaceutical Co.	02-12-1992		

U.S. PATENT DOCUMENTS						
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		Number	Kind Code ² (if known)			
		5,653,961		McNally, et al.	08/05/1997	
		5,658,878		Bäckström, et al.	08-19-1997	
		5,693,338		Milstein	12-02-1997	
		5,740,794		Smith, et al.	04-21-1998	
		5,747,445		Bäckström, et al.	05-05-1998	
		5,763,396		Weiner, et al.	06-09-1998	
		5,785,989		Stanley, et al.	07-28-1998	
		5,785,049		Smith, et al.	07-28-1998	
		5,807,315		Van Antwerp, et al.	09-1998	
		5,849,322		Ebert, et al.	12-15-1998	
		5,874,064		Edwards, et al.	02-23-1999	
		5,877,174		Ono, et al.	03-02-1999	
		5,901,703		Ohki, et al.	05-11-1999	

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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		JP	363020301A		Dainichi Color and Chem	01-1998		
		PCT	0 220 958 A2		Eli Lilly and Company	05-06-1987		
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Sheet	4	of	14	Attorney Docket Number	PDT 120/121 DIV CON

	PCT	WO 90/13285	Enzytech, Inc	11-15-1990	
	PCT	WO 91/16882	Lipsome Technology	11-14-1991	
	PCT	WO 91/04011	Riker Laboratories Inc.	04-04-1991	
	PCT	WO 92/08509	MMM	05-29-1992	
	PCT	WO 93/02712	Danbiosyst	02-18-1993	

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		Number	Kind Code ² (if known)			
		5,912,011		Makino, et al.	06-15-1999	
		5,929,027		Takama, et al.	07-27-1999	
		5,952,008		Bäckström, et al.	09-14-1999	
		5,985,309		Edwards, et al.	11-16-1999	
		5,997,848		Patton, et al.	12-07-1999	
		6,051,256		Platz, et al.	04-18-2000	
		6,063,910		Debenedetti	05-2000	
		6,099,517		Daughterty	09-08-2000	
		6,153,613		Ono, et al.	11-28-2000	
		6,254,854		Edwards, et al.	07-03-2001	
		6,294,204		Rossling, et al.	09-25-2001	
		6,395,774		Milstein	05-28-2002	
		6,423,344		Platz, et al.	07-23-2002	
		6,432,383		Modi	08-13-2002	

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Sheet	5	of	14	Attorney Docket Number	PDT 120/121 DIV CON

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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		PCT	WO 92/04069		Aktiebolaget astra	03-1992		
		PCT	WO 93/17728		Aktiebolaget Astra	09-1993		
		PCT	WO 93/02712		Danbiosyst UK Limited	02-18-1993		
		PCT	WO 93/18754		Pharmaceutical Discovery	09-30-1993		
		PCT	WO 94/000291		Fisons Plc	01-06-1994		

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		Number	Kind Code ² (if known)			
		6,436,443		Edwards, et al.	08-20-2002	
		6,440,463		Feldstein, et al.	08-27-2002	
		6,447,753		Edwards, et al.	09-10-2002	
		6,503,480		Edwards, et al.	01-07-2003	
		6,518,239		Kuo, et al.	02-11-2003	
		6,592,904		Platz, et al.	07-15-2003	
		6,635,283		Edwards, et al.	10-21-2003	
		6,676,931		Dugger, III	01-13-2004	
		6,685,967		Patton	02-03-2003	
		6,737,045		Patton	05-18-2004	
		6,949,258		Zhang	09-24-2005	
		7,030,084		Ekwuribe, et al.	04-18-2006	

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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		PCT	WO 95/00127		Astra Atkiebolag	00-1995		
		PCT	WO 95/11666		Coordinated Drug	05-04-1995		
		PCT	WO 95/31979		R.P Scherer International	11-30-1995		
		PCT	WO 95/34294		Hamilton,Brook,Smith,& Reynolds P.C. and Yissum	12-21-1995		
		PCT	WO 97/49386		Peptide Delivery Systems	12-31-1997		

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		Number	Kind Code ² (if known)			
		RE35,862		Steiner, et al.	07-28-1998	
		RE37,053		Hanes, et al.	02-13-2001	
		2003/0064097		Patel, et al.	04-03-2003	
		2003/0068378		Chen, et al.	04-10-2003	
		2003/0194420		Holl, et al.	10-16-2003	
		2004/0151774		Pauletti, et al.	08-05-2004	
		2004/0247628		Lintz, et al.	12-09-2004	
		2004/157928		Kim Jae-Hwan, et al.	08-12-2004	
		2005/0080000		Thurrow Horst, et al.	04-14-2005	
		6,737,045		Patton	05-18-2004	
		6,949,258		Zhang	09-24-2005	

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		PCT	WO 01/00654		Steiner	01-2001		
		PCT	WO 01/07107		PharmaceuticalDiscovery Corporation	02-01-2001		
		PCT	WO 03/057170		Emisphere Technologies	07-17-2003		
		PCT	WO 03/086345		Atrix Laboratories, Inc.	10-23-2003		
		PCT	WO 03/094951		Novo Nordisk As	11-20-2003		
		PCT	WO 04/056314		Nastech Pharmaceutical Company Inc	07-08-2004		

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		2005/0153874		Cheatham	07-14-2005	
		2004/0096403		Steiner	05-20-2004	
		2003-0017211		Steiner	01-23-2003	
		2004/0096403		Steiner	05-20-2004	
		2005/0214251		Steiner	03-11-2005	
		2007/0086952		Steiner	09-26-2006	
		6,582,728		Platz	06-24-2003	
		2004/0182387		Steiner	09-23-2004	
		2004/0096403		Steiner	05-20-2004	

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		PCT	WO 05/089722		Biodel , Inc	09-29-2005		
		PCT	WO 02/11676		DMI Biosciences, Inc.	02-14-2002		
		PCT	WO 04/075919		Medtronic Minimed, Inc	09-10-2004		

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		BAUER, et al., "Assessment of beta-adrenergic receptor blockade after isamoltane, a 5-HT ₁ -receptor active compound, in healthy volunteers," <i>Clin. Pharmacol Ther</i> 53:76-83 (1993).	
		BENITA, "Characterization of Drug-Loaded Poly(d,l-lactide) Microspheres," <i>J. Pharm. Sci.</i> , 73: 1721-1724 (1984).	
		BENSCH, et al., "Absorption of intact protein molecules across the pulmonary air-tissue barrier," <i>Science</i> 156: 1204-1206 (1967).	
		BRANGE, et al., "Insulin Structure and stability", <i>Pharm Biotechnol.</i> , 5:315-50 (1993).	
		CEFALU, et al, "Inhaled Human Insulin Treatment in Patients with type 2 diabetes mellitus," <i>Ann. Int. Med.</i> , 134: 203-7 (2001).	
		CHEATHAM and PFEUTZNER, "Desirable dynamics & performance of inhaled insulin compared to subcutaneous insulin given at mealtime in type 2 diabetes: A report from the technosphere/insulin study group" <i>Diabetes Technology & Therapeutics</i> 6:234-235 (2004).	
		COSTELLO, et al., "Zinc inhibition of mitochondrial aconitase and its importance in citrate metabolism in prostate epithelial cells", <i>Journ. Biol. Chem.</i> , 272(46):28875-28881 (1997).	
		DIETER KÖHLER, "Aerosols for Systemic Treatment", <i>Lung (Suppl)</i> , 677-684 (1990).	
		DUNN, "Zinc-ligand interactions modulate assembly and stability of the insulin hexamer", <i>Biometals</i> , 18(4):295-303 (2005).	
		ELLIOTT, et al., "Parenteral absorption of insulin from the lung in diabetic children," <i>Austr. Paediatr. J.</i> 23: 293-297 (1987).	

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		Application Number	10/719,734		
		Filing Date	November 21, 2003		
		First Named Inventor	Solomon S. Steiner		
		Group Art Unit	1616		
		Examiner Name	Alstrum Acevedo, James Henry		
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		ENGELGAU, et al., "Screening for type 2 diabetes," <i>Diabetes Care</i> 1563(23):1-31 (2000).	
		FESTA, et al., "LDL particle size in relation to insulin, proinsulin, and insulin sensitivity" <i>Diabetes Care</i> 22(10):1688-1693 (1999).	
		GARBER, "Premixed insulin analogues for the treatment of diabetes mellitus", <i>Drugs</i> , 66(1):31-49 (2006).	
		HAFFNER, et al., "Proinsulin and insulin concentrations in relation to carotid wall thickness" <i>Stroke</i> 29:1498-1503 (1998).	
		HAGEDORN, et al., "Protamine insulin", <i>JAMA</i> , 106:177-180 (1936).	
		HANLEY et al., "Cross-sectional and prospective associations between proinsulin and cardiovascular disease risk factors in a population experiencing rapid cultural transition" <i>Diabetes Care</i> 24(7):1240-1247 (2001).	
		HEUBNER, et al. <i>Klinische Wochenschrift</i> 16,2342 (1924)	
		HEYDER, "Alveolar deposition of inhaled particles in humans," <i>Am. Ind. Hyg. Assoc. J.</i> 43(11): 864-866 (1982).	
		HEYDER, "Particle Transport onto Human Airway Surfaces" <i>Eur. J. Respir. Dis. Suppl.</i> 119, 29-50 (1982)	
		JOHNSON, et al., "Turbuhaler®: a new device for dry powder terbutaline inhalation," <i>Allergy</i> 43(5):392-395 (1988)	
		KOHLER, et al., "Pulmonary Administration . . .", Abstract 298, <i>Diabetes</i> 33 (Suppl.):75A (1984).	

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		KOHLER, "Aerosols for Systemic Treatment", <i>Lung Suppl.</i> 677-683 (1990)	
		KOMADA, et al., "Intratracheal delivery of peptide and protein agents: absorption from solution and dry powder by rat lung," <i>J. Pharm. Sci.</i> 83(6): 863-867 (1994).	
		KONTNY, et al. "Issues Surrounding MDI Formulation Development with Non-CFC Propellants," <i>J. Aerosol Med.</i> 4(3), 181-187 (1991).	
		LEE, et al., "Development of an Aerosol Dosage Form Containing Insulin," <i>J. Pharm. Sci.</i> 65(4), 567-572 (1976).	
		LIM, "Microencapsulation of Living Cells and Tissues," <i>J. Pharm. Sci.</i> , 70: 351-354 (1981).	
		MATHIOWITZ, "Morphology of Polyanhydride Microsphere Delivery Systems," <i>Scanning Microscopy</i> , 4: 329-340 (1990).	
		MATHIOWITZ, "Novel Microcapsules for Delivery Systems," <i>Reactive Polymers</i> , 6: 275-283 (1987).	
		MATHIOWITZ, "Polyanhydride Microspheres As Drug Carriers I. Hot-Melt Microencapsulation," <i>J. Controlled Release</i> , 5: 13-22 (1987).	
		MATHIOWITZ, "Polyanhydride Microspheres As Drug Carriers II. Microencapsulation by Solvent Removal," <i>J. Applied Poly. Sci.</i> , 35: 755-774 (1988).	
		MATHIOWITZ, "Polyanhydride Microspheres IV. Morphology and Characterization of Systems Made by Spray Drying," <i>J. Applied Poly. Sci.</i> , 45: 125-134 (1992).	
		MOREN, <u>Aerosols in Medicine</u> , (2nd ed.), Elsevier, pp. 321-350.	

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				Group Art Unit		1616
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		NAGAI, et al., "Powder Dosage Form of Insulin for Nasal Administration," <i>J. Control Rel.</i> , 1:15-22 (1984).	
		OKUMURA, et al., "Intratracheal delivery of insulin. Absorption from solution and aerosol by rat lung," <i>Int. J. Pharmaceuticals</i> 88: 63-73 (1992).	
		PATTON & PLATZ, "Routes of Delivery: Case Studies. Pulmonary delivery of peptides and proteins for systemic action," <i>Adv. Drug. Del. Rev.</i> 8: 179-196 (1992).	
		PFUTZNER, et al., "Influence of small dose i.v., s.c. and pulmonary insulin treatment on prandial glucose control in patients with type 2 diabetes" <i>37th Annual Meeting of the EASD, Glasgow, 9-13 September 2001</i> 812 (2001) (abstract).	
		PRABHU, et al. "A study of factors controlling dissolution kinetic of zinc complexed protein suspensions in various ionic species," <i>Int. J. Pharm.</i> , 217(1-2):71-8 (2001).	
		RASKIN, et al., "Continuous subcutaneous insulin infusion and multiple daily injection therapy are equally effective in type 2 diabetes" <i>Diabetes Care</i> 26:2598-2603 (2003).	
		ROSENSTOCK, et al., "Reduced hypoglycemia risk with insulin glargine: a meta-analysis comparing insulin glargine with human NPH insulin in type 2 diabetes," <i>Diabetes Care</i> , 28(4):950-5 (2005).	
		SALIB, "Utilization of Sodium Alginate in Drug Microencapsulation," <i>Pharazeutische Industrie</i> , 40(11a): 1230-1234 (1978).	
		SAWHNEY, "Bioerodible Hydrogels Based on Photopolymerized Poly(ethylene glycol)-co-poly(a-hydroxy acid) Diacrylate Macromers," <i>Macromolecules</i> , 26: 581-587 (1993).	
		SCHLUTER, et al., "Pulmonary Administration of Human Insulin in Volunteers and Type I Diabetics," <i>Diabetes</i> , 33 (Suppl.): 298 (1984)	

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		Examiner Name	Alstrum Acevedo, James Henry		
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		SCHNEIDER, et al., "Stimulation by proinsulin of expression of plasminogen activator inhibitor type-I in endothelial cells" <i>Diabetes</i> 41(7):890-895 (1992).		
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		WARREN, et al., "Postprandial versus preprandial dosing of biphasic insulin aspart in elderly type 2 diabetes patients" <i>Diabetes Research and Clinical Practice</i> 66:23-29 (2004).		
		WATERHOUSE, et al. "Comparative assessment of a new breath-actuated inhaler in patients with reversible airways obstruction." <i>Respiration</i> 59:155-158 (1992).		
		WIGLEY, et al., "Insulin across respiratory mucosae by aerosol delivery," <i>Diabetes</i> 20(8): 552-556 (1971).		
		WIGLEY, et al., "Insulin across respiratory mucosae by aerosol delivery," <i>Diabetes</i> 20(8): 552-556 (1971).		
		WITCHERT, "Low Molecular Weight PLA: A Suitable Polymer for Pulmonary Administered Microparticles," <i>J. Microencapsulation</i> , 10(2): 195-207 (1993).		
		YOSHIDA, et al., "Absorption of insulin delivered to rabbit trachea using aerosol dosage form," <i>J. Pharm. Sci.</i> 68(5): 670-671 (1979).		
		ZETHELIUS, et al., "Proinsulin is an Independent Predictor of Coronary Heart Disease" <i>Circulation</i> 105:2153-2158 (2002).		
		BERGE, et al. "Pharmaceutical Salts," <i>J. Pharmaceutical Sciences</i> 66(1):1-19 (1997).		
		HEINEMANN, et al. "Current Status of the development of inhaled insulin" <i>Br. J. Diabetes Vasc Dis</i> 4:295-301 (2004).		
		STEINER, et al. "Technosphere TM / Insulin- proof of concept study with new insulin formulation for pulmonary delivery" <i>Exp. Clin. Endocrinol. Diabetes</i> 110:17-21 (2002).		
		KOHLE, et al. "Non-radioactive approach for measuring lung permeability: inhalation of insulin," <i>Atemw Lungebrk</i> 13:230-232 (1987). (Original in German and English Translation attached).		
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Sheet	14	of	14	Attorney Docket Number	PDT 120/121 DIV CON
RAZ, et al. "Pharmacodynamic and pharmacokinetics of dose ranging effects of oralin versus s.c. regular insulin in Type 1 diabetic patients," <i>Fourth Annual Diabetes Technology Meeting</i> , Philadelphia, PA, 2004.					

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